

**Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs**

National Laboratory Certification Program (NLCP)

Program Document #44

Date: April 25, 2007

Subject: Fee Schedule

This notice provides the new fee schedule for laboratories participating in or applying for certification in the Department of Health and Human Services' National Laboratory Certification Program (NLCP). **The new fee schedule is effective July 10, 2007.**

The NLCP is a self-supporting program and each laboratory is required to pay fees to participate in the program. To maintain this self-supporting certification program, the Division of Workplace Programs periodically reviews all costs associated with the inspection and performance testing (PT) programs to ensure that the fees fully fund the contractor's costs associated with these programs. This review also attempts to establish specific fees that a laboratory must pay to reimburse the contractor for any additional costs directly associated with remedial actions that occur before and after an inspection and after testing PT samples.

The NLCP application fee for new laboratories is being increased from \$1,000 to \$2,000. The \$1,000 application fee has not been increased since it went into effect on July 1, 1998. The current NLCP application requires an applicant laboratory to submit an extensive amount of information and the contractor's effort to review the information and to work with an applicant laboratory to revise, correct, or resubmit information has increased. We believe this increased fee is necessary if the contractor is to continue to work with the applicant laboratories and provide detailed guidance on the information that needs to be submitted or revised before receiving PT samples as part of the certification process.

The fees associated with NLCP inspections are being increased. Fees for initial inspections, 3-month inspections, and Category 1 maintenance inspections are being increased from \$10,600 to \$11,200. The Category 0 maintenance inspection fee is being increased from \$8,600 to \$9,000, the Category 2 maintenance inspection fee is being increased from \$15,500 to \$16,300, and the Category 3 maintenance inspection fee is being increased from \$23,500 to \$24,800. These increases are primarily due to the increase in the costs involved with pre- and post-inspection activities. The Category 4 maintenance inspection fee is being increased from \$32,200 to \$38,000. This increase reflects not only the increase in the costs involved with pre- and post-

inspection activities, but also the increased cost for including an additional data auditor along with the two checklist inspectors and three auditors currently assigned to Category 4 maintenance inspections. The workload for Category 4 laboratories has increased significantly and there is a need to include an additional data auditor on the inspection team to ensure that a sufficient number of drug test results are reviewed. The Category 5 maintenance inspection fee is being increased from \$52,000 to \$62,800. We believe the significant increase in the workload of Category 5 laboratories necessitates a data audit more often than every six months, so we are changing the approach to handling the Category 5 laboratory inspections. Category 5 maintenance inspections will continue on a 6-month schedule, but the inspection team will now consist of two checklist inspectors and four data auditors, rather than the current team of three checklist inspectors and six data auditors. Approximately three months after each 6-month maintenance inspection, there will be an onsite data audit conducted by four data auditors for three days. Due to the large specimen workload in a Category 5 laboratory, any deficiency may impact a large number of donor specimens. The new approach of a data audit every three months is to ensure more timely identification of deficiencies and subsequent remedial action processes, thereby minimizing the number of donor specimens that could be affected by a deficiency. In addition, Category 5 laboratories have had some difficulties accommodating the current 9-person inspection teams (e.g., providing work spaces). It is expected that smaller inspection teams will lessen the burden to the laboratory and facilitate the inspection process. The Category 5 maintenance inspection fee will be collected in two separate payments: \$38,000 for the maintenance inspection (checklist inspection plus data audit) and \$24,800 for the data audit. Category 5 inspections will need to be phased in and depending on the laboratory's inspection cycle, a laboratory may have one final inspection under the previous format and fee schedule. This will be necessary for the transition to a 3 month data audit cycle.

The fee for remedial action after an inspection is being increased from \$2,000 to \$3,000 per incident. The cost for contractor staff to review records and documentation submitted by the laboratory exceeds the current fee. The Division of Workplace Programs believes the fee must be increased to make it self-supporting. A new \$1,000 pre-inspection remedial action fee is established to pay for the additional contractor effort that must be expended for laboratories that fail to submit information by the specified due date and those that submit information that is outdated, incomplete, or in a format that must be revised. We believe this new fee will encourage laboratories to submit the correct information on time and in the required format.

The fees for initial and maintenance sets of PT samples are being increased from \$2,700 to \$3,000. Again, the contractor's costs for activities associated with the PT program (e.g., preparing and shipping the sets of PT samples, analysis of results) have increased.

The current fee associated with PT error remediation is being revised. The remedial fee for a major error is being increased from \$1,600 to \$3,000 and a new \$1,000 fee for a minor error is being established per incident. We believe the increased fee for a major error and the new fee for a minor error is appropriate to reimburse the contractor for the cost associated with working with

the laboratory to investigate and correct each type of error. We have always attempted to minimize the remedial fees associated with errors on PT samples; however, the costs associated even for minor PT errors are significant and must be appropriately charged to the laboratory when an incident occurs that needs remediation.

The new fee schedule is as follows:

	<u>Fee (\$)</u>
Application	2,000
Inspections	
Initial	11,200
3-month Second Initial	11,200
Maintenance	
Category 0	9,000
Category 1	11,200
Category 2	16,300
Category 3	24,800
Category 4	38,000
Category 5 - Inspection	38,000
Category 5 - Audit	24,800
Special	Actual Cost
Remedial Action	
Pre-inspection	1,000
Post-inspection	3,000
Performance Testing	
Initial Set	3,000
Maintenance Set	3,000
Remedial Action	
Major	3,000
Minor	1,000
Lab Withdrawal	9,900 – 16,300
(Final Audit Inspection)	

If you have any questions regarding these changes, please contact my staff at (240) 276-2600 or by email: Donna.Bush@samhsa.hhs.gov

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Robert L. Stephenson II, M.P.H.
Director
Division of Workplace Programs